



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/586,942	06/02/2000	Daniel Flammang	39558/DBP/E43	6577

26694 7590 01/06/2004

VENABLE, BAETJER, HOWARD AND CIVILETTI, LLP
P.O. BOX 34385
WASHINGTON, DC 20043-9998

EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
----------	--------------

3762

DATE MAILED: 01/06/2004

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/586,942

Applicant(s)

FLAMMANG, DANIEL

Examiner

Frances P. Oropeza

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/21/03 (RCE) & 10/22/03 (Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 11/21/03 has been entered.

Response to Amendment filed 10/22/03

2. The Applicant amended independent claim 20 to overcome the rejection of record hence ^{NEW FD} a grounds of rejection is established in the subsequent paragraphs.
A

Claim Rejections - 35 USC § 102/ 35 USC § 103

3. Claims 14 and 19-24 and 26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Altman et al. (US 4726379).

As to claim 20, Mc Gee et al. disclose a multi-site cardiac defibrillation system comprising an electrode arrangement (10) having a lead (12) with an undivided proximal end (14), a distal end (16) and an electrode support assembly (20) with spline elements (22) (branches) (col. 5 @ 66 – col. 6 @ 10). In the figure 6 embodiment, an electrical pulse-discharging device (58) is connected to one or more arrays of electrodes (70), each array having a splitter (72) and branches (67) with a central core structure made of memory wire (a memory member structure). Eight electrodes (67) are disposed on each branch (col. 14 @ 29-61). The number of branches can be eight or fewer, read to be two branches (col. 6 @ 32-36).

The characteristic of “unambiguously associated” electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area. If the plurality of electrodes is read as two electrodes, each branch has a single electrode, hence creating a single region where the two electrodes are unambiguously associated (col. 3 @ 13-20; col. 4 @ 13-19). If the plurality of electrodes is read as to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branches create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 60-65). Note that the concept of contacting the “lateral and septal” regions amounts to an intended use limitation of which McGee is inherently capable of performing.

As to claim 14, the slidable sheath (44) (sliding sleeve) is deployed by adjusting the sheath using a rearward movement (arrow 43) (figures 3 and 4; col. 6 @ 37-63).

As to claim 18, the memory member structure contains titanium (col. 6 @ 8-10).

As to claim 19, the electrode arrangement has three different branches (figure 6).

As to claim 21, the branches each contain eight electrodes (about seven electrically conductive surface portions) (figure 6).

As to claims 22 and 23, the conductive surface portion are ring electrodes, one ring electrode located at the distal end of each branch (col. 14 @ 45-48).

As to claim 24, the electrodes are spaced one centimeter apart (col. 9 @ 53-55).

As noted above, the number of branches can be eight or fewer, read to be two branches, the lateral and septal branches (col. 6 @ 32-36).

As to the conductive surface portions/ electrodes being unambiguously associated in pairs, McGee et al. teach delivering pacing to bands/ stimulation layers using electrodes on the spline elements (col. 9 @ 60-65). If the configuration has only two spline elements each having a single electrode in the individual bands (col. 9 @ 65 - col. 10 @ 2), the pacing involves pairs of electrodes (col. 6 @ 34-36). As previously discussed above, the characteristic of “unambiguously associated” electrodes is accepted to be electrodes from different lead branches grouped to stimulate a defined area. If the plurality of electrodes is read as two electrodes, each branch has a single electrode, hence creating a single region where the two electrodes are unambiguously associated (col. 3 @13-20; col. 4 @ 13-19). If the plurality of electrodes is read as to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branches create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 60-65).

As to the bipolar mode of operation (claim 20), it is accepted that the distinction between unipolar and bipolar pacing modes reflects the distance between the two electrodes. In the unipolar mode, the anode is remotely located (often accomplished by having the simulator housing located in the patient’s thorax serve as the anode) and in the bipolar mode, the anode is located close to the cathode (often accomplished by having both electrodes on lead(s) in the patient’s heart, one electrode serving as an anode). It is inherent that McGee et al. teach using a bipolar mode of pacing for most embodiments because the electrodes are located closely together in the heart (figure 6; col. 9 @ 8-18). McGee provides a unipolar pacing mode (col. 9 @ 34-37).

As to using an anode and a cathode (claim 20), it is accepted that when using a pair of electrodes for cardiac stimulation, the negatively charged electrode, the cathode, is the electrode most closely associated with the point of origin of the cardiac stimulation and the positively charged electrode, the anode, is the electrode more remotely associated with the point of cardiac stimulation. It is inherent, McGee et al. teach using a pair of electrodes to serve as an anode and a cathode.

As to each actuated pair defining layer from the septal branch to the lateral branch (claim 20), McGee et al. teach a plurality of electrodes on each branch. As previously discussed, if the plurality of electrodes is read to be an even number of electrodes, each branch has an equal number of electrodes and the electrodes on the first and second branch create a pair of unambiguously associated electrodes, hence creating bands/ regions of stimulated myocardium/ layers spanning from the electrical conductive surface portion of the septal branch to the electrical conductive surface portion of the lateral branch thereby dividing the cardiac tissue (col. 7 @ 60-64; col. 8 @ 15-21; col. 9 @ 8-11 and 60-65).

In the alternative, given that McGee et al. do not explicitly call for lateral and septal branches, Ljungstrom teaches electrode arrangements using a two limb-shaped structure to uniformly distribute the conductors over the electrode head for the purpose of providing a comparatively large defibrillation area. Based on the location of the limbs/ branches in figure 4, the two branches are named the septal branch (19) and the lateral branch (18). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the McGee branches in the septal and lateral areas of the heart in order to uniformly distribute the electrodes over the atrium providing optimal atrial tissue stimulation (figure 4; page 3 @ 5-11).

In the alternative, given that McGee et al. do not explicitly call for a bipolar pacing mode using an anode and a cathode, Altman teaches that a bipolar mode of operation occurs when both electrodes are located in the heart, rather than one electrode being located remotely. Altman also teaches when a pair of electrodes is used to pace or sense cardiac activity, one electrode serves as an anode and the other electrode serves as a cathode. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the terms bipolar mode of operation and anode and cathode in association with the McGee et al. system in order to use terms known in the art to define the pacing configuration where the both electrodes are located in the heart, one serving as an anode and the other serving as a cathode (col. 1 @ 42-57).

4. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al. (US 5855592) in view of Cookston et al. (US 5834031), or in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Altman et al. (US 4726379) and further in view of Cookston et al. (US 5834031). As discussed in paragraph 3 of this action, McGee et al./modified McGee et al. disclose the claimed invention except for a means for heating the memory member structure.

Cookstone et al. teach lead placement using ohmic heating for the purpose of deflecting the memory member in the lead to enhance electrode contact with a desired heart region. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used ohmic heating in the McGee et al./ modified McGee et al. system in order to effect proper lead contact and to avoid excessive lead implantation cost associate with lead damage and increased operating time (figures 4-6: col. 1 @ 7-20 and 28-31; col. 2 @ 11-39; col. 3 @ 31-45; col. 7 @ 3-65).

Art Unit: 3762

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over McGee et al. (US 5855592) in view of Hess (US 4664120), or in the alternative, under 35 U.S.C. 103(a) as obvious over McGee et al. (US 5855592) in view of Ljungstrom (EP 0 601 328 A 1) and further in view of Altman et al. (US 4726379) and further in view of Hess (US 4664120). As discussed in paragraph 3 of this action, McGee et al./ modified McGee et al. disclose the claimed invention except for the lead configuration including two branches and a ventricular branch with at least one ventricular electrode.

Hess teaches multifunctional lead design using a configuration including two branches and a ventricular branch with at least one ventricular electrode for the purpose of establishing and maintaining reliable contact with portions of the heart undergoing testing and/ or treatment. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a lead configuration including two branches and a ventricular branch with at least one ventricular electrode in the McGee et al./ modified McGee et al. system in order to effectively and efficiently perform multiple functions, such as mapping or pacing, in connection the diagnosing or treatment of cardiac conditions (col. 1 @ 7-13; col. 2 @ 21-31; figures 4 and 5).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Art Unit: 3762

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
12/26/03

Angela D. Sykes

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700